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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/325,189	06/03/99	KINJO	M 990360/LH

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EXAMINER

TUNG, J

ART UNIT

PAPER NUMBER

1656

9

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/325,189

Applicant(s)

Kinjo

Examiner

Joyce Tung

Group Art Unit

1656



☒ Responsive to communication(s) filed on Apr 26, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-38 is/are pending in the application.

Of the above, claim(s) 9-38 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-38 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Claims 9-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
2. Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that Group I and III are identically classified and both methods involves methods of analyzing a target nucleic acid. This is not found persuasive because although both groups are identically classified, two groups are involved different method steps, for example, Group I involves the nucleic acid amplification which uses one primer, while Group III involves an asymmetric amplification where two primers are needed.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3. The title of the invention is not descriptive because the old title of instant invention is directed to a method and apparatus of analyzing a target nucleic acid. The claim language is directed to a method of analyzing a target nucleic acid by applying a nucleic acid amplification. A new title is required that is clearly indicative of the invention to which the claims are directed.

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Claim Rejections - 35 U.S.C. § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-8 are vague and indefinite because of the language "a nucleic acid synthase". If the nucleic acid amplification is a polymerase chain reaction (PCR), the enzyme supposed to be used is a polymerase. Thus it is suggested to use "a nucleic acid polymerase" instead of "a nucleic acid synthase" which is not a term an ordinary skill is recognized in the art. Additionally, regarding the language "substrate molecule", it is suggested to use "nucleotides", if the reaction is PCR.

b. Claims 2-8 are vague and indefinite because of the language "a predetermined measurement area". It is unclear how the language is defined in the specification.

c. Claims 3-8 are vague and indefinite because of the language "a moving amount" in claim 3 and 4. It is unclear whether the amount of the marker is removed or moved. It is suggested to clarify uncertainty.

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- d. Claims 5-8 are vague and indefinite because of the language "performing a arithmetic operation by means of an autocorrelation function". It is unclear how "an autocorrelation function" is defined in the specification.
- e. Claims 1-8 are vague and indefinite because the language "the labeled molecule" in the evaluating step is unclear whether it is the labeled amplified nucleic acid or the labeled substrate molecule. It is suggested to clarify uncertainty.
- f. Claims 3-8 are vague and indefinite because the language "a moving amount of the maker molecule" is unclear whether the maker molecule is determined or the labeled amplified nucleic acid with the marker molecule is determined or the labeled substrate with the marker molecule is determined. It is suggested to clarify uncertainty.
- g. Claims 1-8 are vague and indefinite because the claim language claims that a primer is used in the reaction, while in example 1 of the specification(See pg. 35) there are one forward primer and another reverse primer used in the reaction. It is suggested to clarify uncertainty.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis et al. (4,965,188) in view of Clive et al. (J. Neurosci. Methods, 1998, Vol. 81(1,2), pg. 25-34).

Mullis et al. disclose a process for amplifying any target nucleic acid sequence involving two primers, thermostable enzyme and the amplified nucleic acid sequence can be detected (See the Abstract). In the process nucleotides are labeled so that the resulting amplified sequence is labeled (see column 5, lines 3-5). The amplification can be done with a single primer (See column 11, lines 12-17). The automated machine can be used to handle the amplification process (See column 13, lines 42-62). The final amplified DNA products with labeled nucleotides may be analyzed by electrophoretic separation of any other appropriate method (See column 20, lines 43-51), for example, a Southern blotting technique (See column 20, lines 34-42). The Southern blotting technique can be used to measure a signal from a marker and electrophoretic separation can be used to evaluate the mobility of the amplified DNA.

Mullis et al. do not disclose based on the evaluation results to quantify the amplified target nucleic acid.

Clive et al. disclose RT-PCR used to quantitate the changes in P0 mRNA (See the Abstract).

Mullis et al. do not disclose converting a change of the moving amount into a statistical data based on a plurality of measurement data. However, this is routine practice to do statistical analysis based on the plurality of the measurement data in the art.

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Mullis et al. also do not disclose removing the labeled substrates which are not incorporated in the amplified nucleic acid. This is also routine practice for an ordinary skill in the art to remove the unincorporated nucleotide to reduce background noisy before a measurement.

The teachings of Clive et al. and Mullis et al. suggest the limitations of instant claims 1-8. Instant claims 1-8 are drawn to a method of analyzing a target nucleic acid by a nucleic acid amplification comprising a primer, labeled substrates and synthase, measuring a signal from the marker molecule in the test solution, evaluating mobility of the labeled molecule and quantifying the results from quantification.

One of ordinary skill in the art at the time of the instant invention would have been motivated to combine these two references to make instant invention for a reasonable expectation of success because the method of Mullis et al. is used to amplify any desired target nucleic acid sequence which can be readily detected (See the Abstract) and the detection can be done by detecting the incorporated marker molecule into amplified nucleic acid products and applying electrophoresis to evaluate the mobility or the labeled amplified nucleic acid sequence ,and the method of Clive et al. is for quantification of an amplified nucleic acid sequence and is sensitive (See the Abstract). It would have prima facie obvious to carry out the method as claimed.

Drawings

8. The drawings are approved by draftman. Thus, PTO-948 is not required to be mailed.

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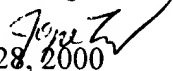
9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

July 28, 2000 


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

7/31/00 